



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

m4274n

WARNING LETTER

September 29, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2000-99

Geraldine McGinty, M.D.
New York Medical Group, P.C.
Bronx Cross County
1010 Central Park Avenue
Yonkers, NY 10704

Facility ID: 186825

Dear Dr. McGinty:

Your facility was inspected on September 19, 2000 by a representative of the New York State Department of Health, acting in behalf of the Food and Drug Administration. This inspection revealed serious regulatory problems involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

- *Processor QC records were missing on 6 consecutive days for the [REDACTED] during the month of November, 1999.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, they represent violations of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

New York Medical Group, P.C.
Warning Letter NYK-2000-99

There was also a Level 2 finding that was listed on the inspection report provided at the close of the inspection. The Level 2 finding was:

- *Processor QC records were missing on 6 out of 24 days of operation or 25% of the total number of days when mammography was conducted during the month of November, 1999 for the [REDACTED]*

We acknowledge receipt of your letter dated September 25, 2000 which relays the change in responsibility for the management of radiological services at your facility from New York Medical Group to Montefiore Medical Center. However, your response does not relay an explanation for the missing records or corrective actions taken to prevent a recurrence of the noncompliances noted.

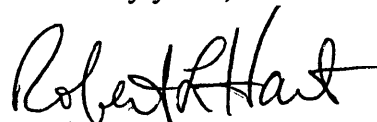
It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct the violations noted in this letter; and
- each step your facility is taking to prevent the recurrence of similar violations.

Please submit your response to the above issues to the attention of Lillian C. Aveta, Compliance Officer, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely yours,



Robert L. Hart
Acting District Director
New York District

New York Medical Group, P.C.
Warning Letter NYK-2000-99

cc: Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

cc: Gerald O'Connor
New York State Dept. of Health
Flanigan Square, Room 530
547 River Street
Troy, NY 12180

cc: Nelson Warren
New York State Dept. of Health
145 Huguenot Street – Suite 500
New Rochelle, NY 10801